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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,609	08/17/2000	Yoshinari Kumagai	BEAR-004	6929

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EXAMINER

MOHAMED, ABDEL A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 01/09/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/642,609

Applicant(s)

KUMAGAI ET AL.

Examiner

Abdel A. Mohamed

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

StatusSUPPLEMENTAL RESTRICTION

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1653

**ACKNOWLEDGMENT OF RESPONSE TO ELECTION OF RESTRICTION
REQUIREMENT AND THE STATUS OF THE CLAIMS**

1. Claims 1-19 are pending in this application. Applicant's remarks with respect to election of the restriction requirement filed 11/4/02 is acknowledged, considered and entered. It is noted that Applicant has elected with traverse Group I (claims 1-16). However, upon further consideration, claims 1-11 have been regrouped as Group I and claims 12-16 as Group II. Thus, the previous election/restriction requirement has been modified as follows:

SUPPLEMENTAL ELECTION/RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. 121:

2. I. Claims 1-11, drawn to a peptidic compounds and a composition thereof comprising one or more moieties that are phosphorylated *in vitro* or *in vivo* by physiologic enzymes and a method of reducing a phosphate level thereof, classified in classes 530 and 436, subclasses 324, 86 and 103, respectively.
- II. Claims 12-16, drawn to a method of treating hyper phosphatemia in an individual by administering the composition recited in claim 12, classified in class 514, subclasses 7 and 12.
- III. Claim 17, drawn to a method of increasing incorporation of phosphorus into bone in an individual by administering the composition recited in claim 17, classified in class 514, subclasses 7 and 12.

Art Unit: 1653

- IV. Claim 18, drawn to a method of increasing bone strength in an individual by administering the composition recited in claim 18, classified in class 514, subclasses 2 and 7.
- V. Claims 19, drawn to a method of treating a bone disease in an individual by administering the composition recited in claim 19, classified in class 514, subclass 7.

The inventions are distinct, each from the other because:

- 3. Inventions I and II-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, methods II-V are alternative methods of use of the peptidic compound and composition thereof of Group I (claims 1-11) as claimed can be used in a materially different process such as in a method of treating hyper phosphatemia, or in a method of increasing incorporation of phosphorus into bone, or in a method of increasing bone strength or in a method of treating a bone disease as claimed in Groups II-V, respectively.
- 4. Inventions II-V, are related as independent methods which are not connected in design, operation or effect. Although, the methods of Groups II-V use the same composition, however, the methods have different functions and different effects. The groups require different patent and literature search and a reference teaching a method of increasing incorporation of phosphorus

Art Unit: 1653

into bone will not teach a method of increasing bone strength nor a method of treating a bone disease and *vice versa*. Thus, the methods of Groups II-V as grouped are independent and distinct inventions which differ in material make up and composition requiring different reaction conditions. Hence, one does not require the other for ultimate use and as such is capable of separate manufacture, use and sale, and is novel and patentable over each other.

5. With respect to compositions of Groups I and II-V, the composition of Group I comprises a peptidic compound having monomer units selected from the group consisting of a coded amino acid, a non-coded amino acid, and a synthetic amino acid of the general structural formula as recited in claim 2 while the compositions of Groups II-V comprises a peptidic compound having 4 to 30 residues which are not defined. Thus, the compositions have different structures, functions and different effects. Hence, one does not require the other for ultimate use and as such is capable of separate manufacture, use and sale, and is novel and patentable over each other.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because the searches for individual subject groups are not coextensive, restriction for examination purposes as indicated is proper.

7. A telephone call was made to Paula Borden on 1/8/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Art Unit: 1653

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

CONCLUSION AND FUTURE CORRESPONDENCE

10. Claims 1-19 are subject to restriction or election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Application/Control Number: 09/642,609

Page 6

Art Unit: 1653

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Abdel H. Mohamed
ABDEL MOHAMED
PATENT EXAMINER
GROUP 1800
TC 1600

AAM Mohamed/AAM
January 8, 2003